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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,527	10/10/2006	David Dakin Iorwerth Wright	07588.0082	7497

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EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
08/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,527	WRIGHT ET AL.	
	Examiner	Art Unit	
	ALI SOROUSH	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 28-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26 and 28-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed on 05/01/2008 and supplemental response filed on 06/25/2008 to the Office Action mailed on 11/01/2007 is acknoweldged.

Status of the Claims

Claims 17, 18, 26, 31, and 34-36 currently amended, claim 27 is cancelled, and claims 37-39 is newly added. Therefore, claims 1-26 and 28-39 is currently pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. The rejection of claims 1-26 and 28-36 under 35 U.S.C. 103(a) as being unpatentable over Osman et al. (International Application Published Under the PCT, Published 12/07/2000) **is maintained**.

Applicant Claims

Applicant claims foam comprising a sclerosing agent and gas phase of 0.0001 to 0.8% nitrogen gas and at least one physiologically acceptable gas; a canister comprising the components of the foam and method of making the canister. Applicant further claims a method treating a patient with an injection of the foam.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Osman et al. teaches a microfoam comprising a physiologically acceptable gas that is dispersible in the blood and an aqueous sclerosant liquid wherein the sclerosant is aqueous polidocanol, the concentration of polidoconal being from 0.5 to 4% vol/vol in the liquid. The microfoam is characterized in that it has a density of 0.11 to 0.14 g/ml and a half-life of at least 2 minutes, more preferably 2.5 minutes, and most preferably 3 minutes. The more preferable physiologically acceptable blood dispersible gas comprises 70 to 80% vol/vol oxygen and 20 to 30% vol/vol carbon dioxide. Which may also comprise a minor portion of nitrogen gas. (See claims 49, 51, 55, and 58 and page 9, paragraph 1and 3). Osman et al. further teaches a device for producing a microfoam where the chamber is pressurized at 0.01 to 0.9 bar over atmospheric pressure and comprises pressurized source of physiologically acceptable gas and upon an activation

mechanism the gas being contacted with aqueous sclerosant liquid wherein the microfoam passes through a passage of cross-sectional dimension 0.1 to 30μm, preferably 5 to 25μm, and more preferably 10 to 20μm. (See claims 19, 20, 21 and 30 and page 11, paragraph 1). The canister is made by the method comprising pre-purging with 100% oxygen for 1 minute, filling the canister with 15 ml of sclerosing agent, and pressurizing with oxygen of 1.7 bar over atmospheric pressure and maintained at this pressure through the use of the canister. (See page 24, example 2). Osman et al. further teaches a method of treating a patient in need of sclerotherapy of a blood vessel comprising administering a microfoam to the blood vessel. The canister is such that it contains sufficient gas and solution to form up to 500ml of microfoam, more preferably 1 to 200 ml and most preferably 10 to 60 ml of microfoam to treat at least one varicosed human saphenous vein. (See claim 65 and page 19, paragraph 5).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Osman et al. teaches a gas phase comprising carbon dioxide, oxygen, and minor amount of nitrogen gas. However, Osman et al. does not anticipate a gas phase comprising 0.0001 to 0.8% nitrogen gas but does make such a gas phase obvious.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have a gas phase comprising a mixture of carbon dioxide, oxygen, and 0.01 to 0.6% of nitrogen gas. One would have been motivated to use such a

composition because Osman et al. teaches a gas phase comprising preferably 70 to 80% oxygen, 20 to 30% carbon dioxide, and a minor amount of nitrogen. It would therefore mean that the composition may comprise between 0 to 10% nitrogen which covers the instantly claimed concentration of 0.01 to 0.6% nitrogen. For the foregoing reasons the instantly claimed invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Response to Applicant's Arguments

Applicant argues that the "Nothing in the prior art suggested that by minimizing the percentage of nitrogen to extremely low levels currently claimed, the size of any enduring bubbles could be reduced to a level where their physiological impact can be eliminated or at least rendered insignificant." And further, that it is the applicants position that they have found unexpectedly that by controlling the percentage of nitrogen gas in the mixture dictates the size of the bubbles formed and thereby effect the physiological effects of the sclerosing foam. Applicant's argument has been fully considered but found not to be persuasive. It is the Examiners position that the prima facia case of obviousness still holds and applicants have not provided a proper side by side comparison of a foam comprising liquid sclerosing agent and a gas phase comprising 0.0001% to 0.8% nitrogen by volume and at least one other physiologically acceptable gas to a foam comprising liquid scelerosing agent and a gas phase comprising a physiologically acceptable gas and nitrogen gas concentrations outside the instantly claimed range taught by Osman et al. in order to show unexpected results.

For the foregoing reasons, the rejection of claims 1-26 and 28-36 under 35 U.S.C. 103(a) is maintained.

New Grounds of Rejection

2. Claims 37-39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osman et al. (International Application Published Under the PCT, Published 12/07/2000) in view of Frullini et al. (Sclerosing Foam in the Treatment of Varicose Veins and Telengiectases: History and Analysis of Safety and Complications, Published 01/2002).

Applicant Claims

Applicant claims foam comprising a sclerosing agent and gas phase of 0.0001 to 0.8% nitrogen gas and at least one physiologically acceptable gas. Wherein the gas bubbles of the foam are no greater than 500μm and are primarily less than 280μm in diameter.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Osman et al. is disclosed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Osman et al. is silent as the size of the gas bubbles of the foam. This deficiency is cured by Frullini et al.

Frullini et al. teach, "The definition of a sclerosing foam (SF) is a mixture of gas and liquid sclerosing solution (detergent type) with tension-active properties. The gas

must be well tolerated or physiologic and the bubble size less than 100μ." (See page 11, Column 1, Lines 5-8). Frullini et al. further teaches that there is "a higher rate of side effects" due to "the large size of the bubbles which easily spread along vessels." (See page 12, Column 1, Lines 28-30).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention combine the teachings of Osman et al. with Frullini et al. Therefore, one of ordinary skill in the art at the time of the instant invention would through routine optimization arrive at the instant claimed bubble size diameter in light of the teachings of Frullini et al. One would have been motivated to do so in order to provide foam that has a minimal amount of side effects. For the foregoing reasons the instantly claimed invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616